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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

2-16-05
Action Date 2-17-05
J. [Signature]

[Docket No. 2003F-0023]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Acacia (Gum Arabic)

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of acacia (gum arabic) as a thickener, emulsifier, or stabilizer in alcoholic beverages at a maximum use level of 20 percent. This action is in response to a petition filed by Kerry, Inc.

DATES: This rule is effective [*insert date of publication in the Federal Register*]. Submit written objections and requests for a hearing by [*insert date 30 days after date of publication in the Federal Register*]. The Director of the Office of the **Federal Register** approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in 21 CFR 172.780 as of [*insert date of publication in the Federal Register*].

ADDRESSES: You may submit written objections and requests for a hearing, identified by Docket No. 2003F-0023, by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

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- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.
- E-mail: fdadockets@oc.fda.gov. Include Docket No. 2003F-0023 in the subject line of your e-mail message.
- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]:
Division of Dockets Management (HFA-305), Food and Drug Administration,
5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All objections received will be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For detailed instructions on submitting objections, see the “Objections” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mical Honigfort, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1278.

SUPPLEMENTARY INFORMATION:

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I. Background

The petition was initially filed as a generally recognized as safe (GRAS) affirmation petition (GRASP 3G0287) as announced in a notice published in the **Federal Register** on October 13, 1983 (48 FR 46626). The GRAS affirmation petition was filed by Beatrice Foods Co. (now Kerry, Inc.) and proposed to amend part 184 (21 CFR part 184) in § 184.1330 *Acacia (gum arabic)* to permit the use of gum acacia (arabic) in alcoholic beverages up to a maximum level of 20 percent in the finished preparation (liqueur).

In a letter dated September 21, 2000, Kerry, Inc., requested that FDA convert the filed GRAS affirmation petition to a GRAS notice in accordance with the agency's proposed rule for Substances Generally Recognized as Safe published April 17, 1997 (62 FR 18938). Consistent with this request, FDA converted the GRAS affirmation petition to GRAS Notice No. GRN 000058. In its evaluation of this GRAS notice (Ref. 1), the agency considered that § 184.1(b)(2) was established at the same time that the GRAS status of some uses of acacia were affirmed and that the limitations in § 184.1(b)(2) were

intended to apply to the GRAS listing for acacia. According to § 184.1(b)(2), if an ingredient is affirmed as GRAS with specific limitations on the conditions of use, any use of the ingredient not in full compliance with the limitations requires a food additive regulation. Given the options discussed in the agency response letter to GRN 000058 (Ref. 1), Kerry, Inc., requested in a letter dated September 6, 2001, that FDA convert GRN 000058 to a food additive petition.

In a notice published in the **Federal Register** on February 13, 2003 (68 FR 7381), FDA announced that a food additive petition (FAP 1A4730) had been filed by Kerry, Inc., c/o Bell, Boyd, and Lloyd, LLC, Three First National Plaza, 70 West Madison St., suite 3300, Chicago, IL 60602–4207. The petition proposes to amend the food additive regulations in part 172 (21 CFR part 172) to provide for the safe use of acacia (gum arabic) as a thickener, emulsifier, or stabilizer in the manufacture of creamers for use in alcoholic beverages at a maximum use level of 20 percent.

II. Introduction

A. Identity

Acacia is the dried gummy exudate from stems and branches of trees of various species of the genus *Acacia*, family *Leguminosae*. Numerous species have been attributed to this genus. Most of the acacia used in the United States is obtained from *Acacia senegal*. The gum consists of the calcium, magnesium, and potassium salts of arabic acid, a polysaccharide acid. The polysaccharide is a sugar polymer that is composed of L-arabinose, D-galactose, L-rhamnose, and D-glucuronic acid. The relative proportions of the sugars differ among different species of acacia.

B. Regulated Food Uses

In the **Federal Register** of September 23, 1974 (39 FR 34203), FDA published a proposed rule to affirm that the use of acacia as a direct human food ingredient is GRAS, with specific limitations. In the **Federal Register** of December 7, 1976 (41 FR 53608), FDA issued a final rule based on this proposal, amending the regulations in part 121 (21 CFR part 121) to affirm that acacia (gum arabic) is GRAS. In the **Federal Register** of March 15, 1977 (42 FR 14302 at 14653), acacia (gum arabic) was redesignated from § 121.104(g)(19) to part 184 by adding § 184.1330 *Acacia (gum arabic)*. Under § 184.1330, acacia is affirmed as GRAS for use in various specific food categories at levels ranging from 1.3 to 85.0 percent. Use of acacia in all other food categories, including alcoholic beverages, is currently limited to not more than 1.0 percent.

The petitioner in this proceeding has requested the approval of the use of acacia as a thickener, emulsifier, or stabilizer in alcoholic beverages at a use level not to exceed 20 percent in the final beverage.

III. Safety Evaluation

In order to establish, with reasonable certainty, that a new food additive is not harmful under its intended conditions of use, FDA considers the projected human dietary exposure to the additive, the additive's toxicological data, and other relevant information available to the agency.

A. Proposed Use and Exposure

The petitioner proposes to use acacia in alcoholic beverages where a creamy consistency was desired. The petitioner relies on the 1973 report of the Select Committee on GRAS Substances (the Select Committee) (Ref. 2, p. 2) and the previously approved uses of acacia under § 184.1330 to demonstrate

that acacia is effective as a thickener, emulsifier, or stabilizer in alcoholic beverages.

The petitioner estimates that the exposure to acacia from the proposed use would be 0.75 gram per person per day (g/p/d) based on these factors: (1) The total number of cases of cordials, liqueurs, and prepared cocktails (which are the types of beverages likely to contain acacia) sold in the United States in 1992, (2) the portion of the population that could legally drink alcoholic beverages in the United States in 1980, and (3) the acacia use-level range in such beverages of 12 to 20 percent. Based on the legal drinking-age limit, only a subset of the population will be exposed to acacia in alcoholic beverages.

FDA has reviewed the petitioner's exposure data and concurs that the proposed use of acacia in alcoholic beverages will increase intake for that subset of the population that consumes these alcoholic beverages by no more than 0.75 g/p/d (Ref. 3), an increase of approximately 30 percent over the cumulative estimated daily intake of acacia for existing uses, estimated previously to be 2.5 g/p/d (Ref. 4).

B. Safety Assessment

The petitioner relied on toxicological data contained in the 1973 report of the Select Committee (Ref. 2) to support the safety of the use of acacia in alcoholic beverages. In its report, the Select Committee evaluated all of the available safety information on acacia and concluded that acacia poses no safety hazard to the public when it is used at the then current levels (Ref. 2, p. 10). The Select Committee believed, however, that because of the potential for allergies to acacia, it was not possible without additional data to determine whether significant increases in consumption of acacia would constitute a dietary hazard (Ref. 2, pp. 9 and 10).

FDA conducted literature searches that updated the information that had formed the basis of the Select Committee report. The agency reviewed toxicological data from a 1982 National Toxicology Program (NTP) report of 2-year carcinogenicity feeding studies on acacia in F344 rats and B6C3F1 mice. The agency evaluated the carcinogenicity of acacia and concluded that F344 rats and B6C3F1 mice consuming diets containing up to 5-percent acacia for 2 years showed no increased incidences of tumors at any site (Ref. 5).

The Joint FAO/WHO (Food and Agriculture Organization/World Health Organization) Expert Committee on Food Additives (JECFA) evaluated acacia for acceptable daily intake and did not place a limit on acacia's dietary use beyond the criterion that it should be used within the bounds of good manufacturing practice, i.e., it should be technologically efficacious and should be used at the lowest level necessary to achieve this effect, it should not conceal inferior food quality or adulteration, and it should not create nutritional imbalance (Ref. 6).

In 1983, 1987, 1988, and 1992, the agency conducted searches of the scientific literature on acacia with a special emphasis on potential hypersensitivity and allergic reaction. Based on a review of the reference materials obtained through these literature searches, the agency concluded that while there was evidence that acacia is associated with dermal/bronchial hypersensitivity in workers handling acacia dust in the workplace (e.g., printing industry), the evidence for the allergic potential of acacia was extremely weak (Refs. 7 and 8).

Based on its review of the safety data (Ref. 9), FDA concludes that the additional use of acacia in alcoholic beverages is safe.

IV. Conclusions

From the review of the available information, the agency concludes that acacia may be safely used as a thickener, emulsifier, or stabilizer in alcoholic beverages at a maximum use level of 20 percent in the final beverage.

Therefore, the regulations in part 172 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

V. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 1A4730 (68 FR 7381). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

VI. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. References

The following references have been placed on display in the Division of Dockets Management (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Letter from A. Rulis, Office of Food Additive Safety, to J. Lemker, Bell, Boyd, and Lloyd, LLC, "Agency Response Letter, GRAS Notice No. GRN 000058," October 1, 2001, Internet address: <http://www.cfsan.fda.gov/~rdb/opa-g058.html>.
2. Select Committee on GRAS Substances, Life Sciences Research Office, Federation of American Societies for Experimental Biology, "Evaluation of the Health Aspects of Gum Arabic as a Food Ingredient," March, 1973.
3. Memorandum from M. DiNovi, Chemistry Review Branch, to R. Martin, Direct Additives Branch, "GRP 3G0287: Beatrice Foods. Gum Arabic as a Stabilizer in Alcoholic Beverage Mixes," March 7, 1994.
4. Memorandum from J. Modderman, Food Additive Chemistry Review Branch, to L. Mansor, GRAS Review Branch, "GRASP 3G0287—Gum Arabic. Beatrice Foods Co.," November 21, 1983.
5. Memorandum of Conference, Cancer Assessment Committee Meeting, "Gum Arabic," January 6, 1998.
6. "Toxicological Evaluation of Certain Food Additives and Contaminants," WHO Food Additives Series 26, No. 686, 1990.
7. Memorandum from J. Griffiths, Additives Evaluation Branch, to C. Coker, Case and Advisory Branch, "Gum Arabic and Immunogenicity; updated literature survey," March 8, 1988.
8. Memorandum from J. Griffiths, Additives Evaluation Branch, to E. Flamm, Direct Additives Branch, "Gum Arabic and Immunogenicity; literature from Dr. D. M. W. Anderson," November 9, 1988.
9. Memorandum from C. Johnson, Additives Evaluation Branch #1, to R. Martin, Direct Additives Branch, "Gum Arabic in Alcoholic Beverages: Final Toxicology Evaluation," April 8, 1996.

VIII. Objections

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) written or electronic

objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 172

Food additives, Incorporation by reference, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

■ 1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

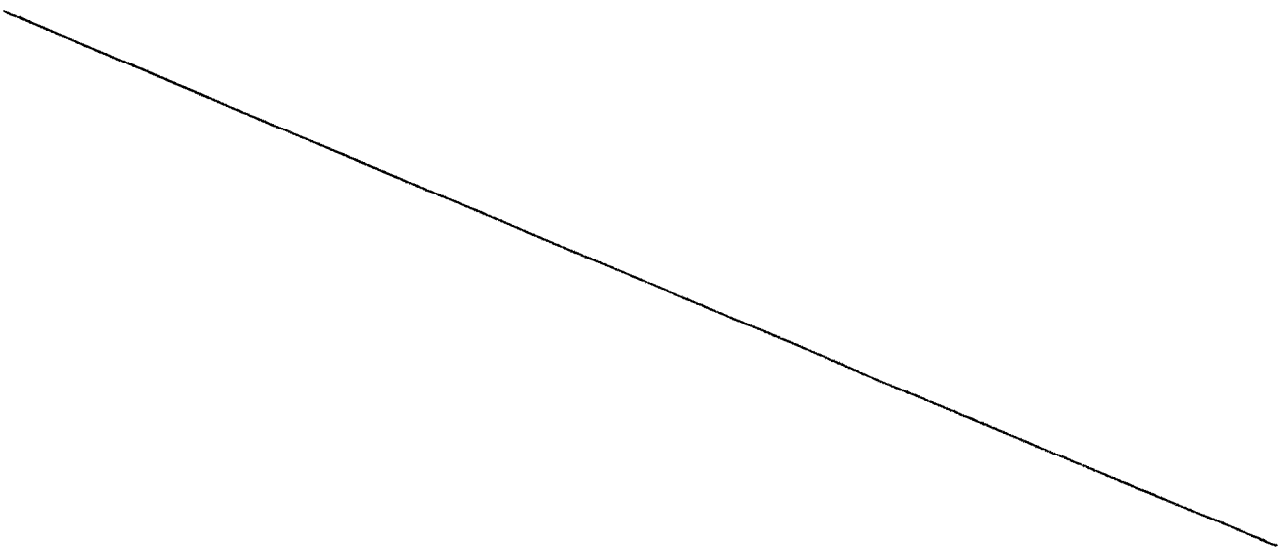
■ 2. Section 172.780 is added to subpart H to read as follows:

§ 172.780 Acacia (gum arabic).

The food additive may be safely used in food in accordance with the following prescribed conditions:

(a) Acacia (gum arabic) is the dried gummy exudate from stems and branches of trees of various species of the genus *Acacia*, family Leguminosae.

(b) The ingredient meets the specifications of the “Food Chemicals Codex,” 5th Ed. (2004), pp. 210 and 211, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the National Academies Press, 500 Fifth St. NW., Washington, DC 20001 (Internet address: <http://www.nap.edu>). Copies may be examined at the Center for Food Safety and Applied Nutrition’s Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.



(c) The ingredient is used as a thickener, emulsifier, or stabilizer in alcoholic beverages at a use level not to exceed 20 percent in the final beverage.

Dated: Nov. 16, 2004
November 16, 2004.

Leslye M. Fraser

Leslye M. Fraser,
Director,
Office of Regulations and Policy,
Center for Food Safety and Applied Nutrition

1 [FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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